

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **INFUVITE ADULT (PHARMACY BULK PACKAGE)** safely and effectively. See full prescribing information for **INFUVITE ADULT (PHARMACY BULK PACKAGE)**.

INFUVITE ADULT PHARMACY BULK PACKAGE

Initial U.S. Approval: 2003

INDICATIONS AND USAGE

INFUVITE ADULT (PHARMACY BULK PACKAGE) is a multivitamin indicated for:

- Prevention of vitamin deficiency in adults and children aged 11 and older receiving parenteral nutrition (1)

DOSAGE AND ADMINISTRATION

- Add the contents of Vial 1 to the contents of Vial 2. Take 10 ml from Vial 2 (the daily dose) and add to not less than 500 mL, and preferably 1000 mL, of intravenous dextrose, saline or similar infusion solutions. Discard any unused portion (2)

DOSAGE FORMS AND STRENGTHS

- Injection for intravenous administration
- One each of Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial) (3)

CONTRAINDICATIONS

- Hypersensitivity to any of the vitamins in the product (4)
- Existing hypervitaminosis (4)

WARNINGS AND PRECAUTIONS

- This product contains aluminum that may be toxic (5.1).
- Allergic reactions to thiamine may occur (5.2).
- Hypervitaminosis A has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease (5.3)
- Vitamin K antagonizes the anticoagulant action of warfarin (5.4).
- Interference with the diagnosis of megaloblastic anemia (5.5).
- Blood vitamin concentrations should be periodically monitored to determine if deficiencies or excesses are developing (5.6)
- Interference with urine glucose testing (5.7)
- Incompatibility with intravenous fat emulsions (5.8)

ADVERSE REACTIONS

There have been reports of the following types of reactions:

- Allergic – anaphylactoid reactions following large intravenous doses of thiamine, urticaria, shortness of breath, wheezing and angioedema (6)

- Dermatologic : rash, erythema, pruritis (6)
- CNS: headache, dizziness, agitation, anxiety (6)
- Ophthalmic : diplopia (6)

To report **SUSPECTED ADVERSE REACTIONS**, contact **Sandoz Inc.** at **1-800-525-8747** or **FDA** at **1-800-FDA-1088** or www.fda.gov/medwatch

DRUG INTERACTIONS

A number of interactions between vitamins and drugs have been reported. The following are examples of these interactions:

Physical Incompatibilities:

- Acetazolamide (2.4)
- Intravenous chlorothiazide sodium (2.4)
- Aminophylline (2.4)
- Ampicillin (2.4)
- Moderately alkaline solutions (2.4)
- Tetracycline HCl (2.4)
- Calcium salts such as calcium gluconate (2.4)
- Vitamin K bisulfite or sodium bisulfite (2.4)

Clinical interactions affecting levels of co-administered drugs

- Antibiotics -Activity of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin decreases by thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid. Ascorbic acid and riboflavin also reduces the activity of bleomycin (7.1)
- Levodopa exposure may decrease by pyridoxine. Levodopa efficacy may decline (7.1)
- Phenytoin exposure may decrease by folic acid increasing the risk of seizure activity (7.1)

Clinical interactions affecting vitamin levels

- Chloramphenicol may inhibit hematologic response to vitamin B12 therapy in pernicious anemia patients (7.2)
- Phenytoin may decrease folic acid concentrations; therefore, coadministration should be avoided in pregnancy (7.2)

USE IN SPECIFIC POPULATIONS

- **Pregnant and Nursing Women:** Pregnant and lactating women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant or nonlactating women (8.1, 8.3)
- **Pediatric Use:** Safety and effectiveness in children below the age of 11 years have not been established (8.4).
- **Renal Impairment:** Monitor renal function, calcium, phosphorus and vitamin A levels in patients with renal impairment (8.6)
- **Hepatic Impairment:** Monitor vitamin A level in patients with liver disease, high alcohol consumption (8.7)

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Revised: 12/2012

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

INFUVITE ADULT (PHARMACY BULK PACKAGE) is indicated for the prevention of vitamin deficiency in adults and children aged 11 and older receiving parenteral nutrition

The physician should not await the development of clinical signs of vitamin deficiency before initiating vitamin therapy.

2 DOSAGE AND ADMINISTRATION

INFUVITE ADULT (PHARMACY BULK PACKAGE) is ready for immediate use in adults and children aged 11 years and older when added to intravenous infusion fluids. Do not administer INFUVITE ADULT (PHARMACY BULK PACKAGE) as a direct, undiluted intravenous injection as it may give rise to dizziness, faintness, and possible tissue irritation.

2.1 Starting Dose, Dose Range and Route of Administration

The starting dose is one 10 mL daily dose that is prepared by transferring the content of vial 1 into the content of vial 2 to provide 10 single doses. One 10 mL dose is then added directly to the intravenous fluid [*see Dosage and Administration (2.3)*]. Patients with multiple vitamin deficiencies or with increased vitamin requirements may need multiple daily dosages as indicated. Some patients do not maintain adequate levels of certain vitamins when this formulation in recommended amounts is the only source of vitamins

2.2 Monitoring

Blood vitamin concentrations should be monitored to ensure maintenance of adequate levels, particularly in patients receiving parenteral multivitamins as the only source of vitamins for long periods of time.

2.3 Instructions for Intravenous Administration

The solution must be prepared prior to intravenous administration. Preparation of INFUVITE ADULT (PHARMACY BULK PACKAGE) for intravenous feeding should be done by transferring the contents of Vial 1 into the contents of Vial 2 to provide ten 10 mL single doses. One daily 10 mL dose should be added directly to not less than 500 mL, and preferably 1000 mL, of intravenous dextrose, saline or similar infusion solutions. Discard any unused portion.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

After INFUVITE ADULT (PHARMACY BULK PACKAGE) is diluted in an intravenous infusion, the resulting solution should be refrigerated unless it is to be used immediately. The solution should be used within 24 hours after dilution. Some of the vitamins in this product, particularly A, D and riboflavin, are light sensitive; therefore, exposure to light should be minimized. Once closure system has been compromised, withdrawal of container contents should be completed within 4 hours.

INFUVITE ADULT (PHARMACY BULK PACKAGE) is a pharmacy bulk package. It is not intended for direct infusion. Discard unused portion.

Directions for Dispensing From Pharmacy Bulk Vial

The Pharmacy Bulk Vial is intended for single puncture, multiple dispensing and for intravenous use only. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion. The Pharmacy Bulk Package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Dispensing from Pharmacy Bulk Vial should be completed as soon as possible after initial entry.

2.4 Drug Incompatibilities

INFUVITE ADULT (PHARMACY BULK PACKAGE) is not physically compatible with moderately alkaline solutions such as a sodium bicarbonate solution and other alkaline drugs such as acetazolamide sodium, aminophylline, ampicillin sodium, tetracycline HCl and chlorothiazide sodium.

Folic acid is unstable in the presence of calcium salts such as calcium gluconate.

Vitamin A and thiamine in INFUVITE ADULT (PHARMACY BULK PACKAGE) may react with bisulfite solutions such as sodium bisulfite or vitamin K bisulfate. Patients should be monitored for vitamin A and thiamine deficiencies.

Consult appropriate references for listings of physical and chemical compatibility of solutions and drugs with the vitamin infusion. In such circumstances, admixture or Y-site administration with vitamin solutions should be avoided.

3 DOSAGE FORMS AND STRENGTHS

INFUVITE ADULT (PHARMACY BULK PACKAGE) is an injection for intravenous administration and is a sterile product consisting of two vials labeled Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial). The mixed solution (100 mL) will provide ten 10 mL single doses.

4 CONTRAINDICATIONS

INFUVITE ADULT (PHARMACY BULK PACKAGE) is contraindicated in patients who have an existing hypervitaminosis, or a history of hypersensitivity due to any vitamins or excipients contained in this formulation.

Allergic reactions have been known to occur following intravenous administration of thiamine and vitamin K.

5 WARNINGS AND PRECAUTIONS

5.1 Aluminum Toxicity

INFUVITE ADULT (PHARMACY BULK PACKAGE) contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solution, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

5.2 Allergic Reactions to Thiamine

Allergic reactions such as urticaria, shortness of breath, wheezing and angioedema have been reported following intravenous administration of thiamine, which is found in INFUVITE ADULT (PHARMACY BULK PACKAGE). There have been rare reports of anaphylactoid reactions following intravenous doses of thiamine. No fatal anaphylactoid reactions associated with INFUVITE ADULT (PHARMACY BULK PACKAGE) have been reported

5.3. Hypervitaminosis A

Hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease. Therefore, supplementation of renal failure patients and patients with liver disease with vitamin A, an ingredient found in INFUVITE ADULT, should be undertaken with caution [See *Use in Specific Populations* (8.5. and 8.6)].

5.4 Vitamin K Antagonizes the Anticoagulant Action of Warfarin

Vitamin K, which is found in INFUVITE ADULTS (PHARMACY BULK PACKAGE) antagonizes the anticoagulant action of warfarin. In patients who are on warfarin anticoagulant therapy receiving parenteral multivitamins such as with

INFUVITE ADULT (PHARMACY BULK PACKAGE) blood levels of prothrombin/INR should be periodically monitored to determine if dose of warfarin needs to be adjusted.

5.5 Interferes with Diagnosis of Megaloblastic Anemia

Do not administer INFUVITE ADULTS (PHARMACY BULK PACKAGE) to patients with suspected or diagnosed megaloblastic anemia prior to blood sampling for the detection of the folic acid and cyanocobalamin deficiencies. The folic acid and the cyanocobalamin in the INFUVITE ADULTS (PHARMACY BULK PACKAGE) solution can mask serum deficits of folic acid and cyanocobalamin in these patients

5.6 Monitor Blood Vitamin Concentrations to Determine if Deficiencies or Excesses are Developing

In patients receiving parenteral multivitamins such as with INFUVITE ADULTS (PHARMACY BULK PACKAGE) , blood concentration should be periodically monitored to determine if deficiencies or excesses are developing. INFUVITE ADULTS (PHARMACY BULK PACKAGE) may not correct long-standing specific vitamin deficiencies. The administration of additional therapeutic doses of specific vitamins may be required [*see Dosage and Administration (2.2)*].

5.7 Interference with Urine Glucose Testing

INFUVITE ADULT (PHARMACY BULK PACKAGE) contains vitamin C which is also known as ascorbic acid. Ascorbic acid in the urine may cause false negative urine glucose determinations

5.8 Incompatibility with Intravenous Fat Emulsions

Do not add INFUVITE ADULT (PHARMACY BULK PACKAGE) directly to intravenous fat emulsions.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other section of the labeling.

- Allergic and anaphylactoid reactions following intravenous administration of thiamine [*see Warnings and Precautions (5.2)*].
- Hypervitaminosis A [*see Warnings and Precautions (5.3)*]

Other adverse reactions:

Dermatologic: rash, erythema, pruritis

CNS: headache, dizziness, agitation, anxiety

Ophthalmic : diplopia

7 DRUG INTERACTIONS

A number of interactions between vitamins and drugs have been reported. Consult appropriate references for additional specific vitamin-drug interactions. The following are examples of these types of interactions:

7.1 Clinical interactions affecting levels of co-administered drugs

Folic Acid

Phenytoin metabolism may be increased by folic acid. Folic acid may lower the serum concentration of phenytoin resulting in increased seizure activity.

Patient's response to methotrexate therapy may be decreased by folic acid.

Pyridoxine

The metabolism of levodopa may be increased and its efficacy may be decreased by pyridoxine.

Antibiotics

Antibiotic activity of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin is decreased by thiamine, riboflavin, pyridoxine, niacinamide, and ascorbic acid. Bleomycin is inactivated *in vitro* by ascorbic acid and riboflavin.

7.2 Clinical interactions affecting vitamin levels

Hydralazine, Isoniazid

Pyridoxine requirements may be increased by concomitant administration of hydralazine or isoniazid.

Chloramphenicol

In patients with pernicious anemia, the hematologic response to vitamin B12 therapy may be inhibited by concomitant administration of chloramphenicol.

Phenytoin

Serum folic acid concentrations may be decreased by phenytoin and, therefore it should be avoided in pregnancy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

INFUVITE ADULT (PHARMACY BULK PACKAGE) has not been studied in pregnant women. Pregnant women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirements may exceed those of nonpregnant women.

8.3 Nursing Mothers

INFUVITE ADULT (PHARMACY BULK PACKAGE) has not been studied in lactating women. Lactating women should follow the U.S. Recommended Daily Allowances for their condition, because their vitamin requirement may exceed those of nonlactating women. Caution should be exercised when INFUVITE ADULT (PHARMACY BULK PACKAGE) is administered to a nursing mother.

8.4 Pediatric Use

Safety and effectiveness in children below the age of 11 years have not been established.

8.5 Geriatric Use

Safety and effectiveness for geriatric use have not been established.

8.6 Renal Impairment

INFUVITE ADULT (PHARMACY BULK PACKAGE) has not been studied in patients with renal impairment. Monitor renal function, calcium, phosphorus and vitamin A levels in patients with renal impairment [*see Warning and Precautions (5.4)*].

8.7 Hepatic Impairment

INFUVITE ADULT (PHARMACY BULK PACKAGE) has not been studied in patients with liver impairments. Monitor vitamin A level in patients with liver disease, high alcohol consumption [*see Warning and Precautions (5.4)*].

10 OVERDOSAGE

Signs and symptoms of acute or chronic overdosage may be those of individual INFUVITE ADULT (PHARMACY BULK PACKAGE) component toxicity.

11 DESCRIPTION

INFUVITE ADULT (PHARMACY BULK PACKAGE) is a sterile product consisting of 2 vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial), provided as a pharmacy bulk package.

A pharmacy bulk package is a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for intravenous infusion.

Each 5 mL of Vial 1 contains:

Ascorbic acid (Vitamin C)200 mg
Vitamin A* (as palmitate)3,300 IU
Vitamin D ₃ * (cholecalciferol)200 IU
Thiamine (Vitamin B ₁) (as the hydrochloride)	6 mg
Riboflavin (Vitamin B ₂) (as riboflavin 5-phosphate sodium)3.6 mg
Pyridoxine HCl (Vitamin B ₆)	6 mg
Niacinamide40 mg
Dexpanthenol (as <i>d</i> -pantothenyl alcohol)15 mg
Vitamin E* (<i>dl</i> - α -tocopheryl acetate)	10 IU
Vitamin K ₁ *150 mcg

Inactive ingredients: 1.4% polysorbate 80, sodium hydroxide and/or hydrochloric acid for pH adjustment, and water for injection.

*Polysorbate 80 is used to water solubilize the oil-soluble vitamins A, D, E, and K.

Each 5 mL of Vial 2 contains:

Folic acid600 mcg
Biotin60 mcg
Vitamin B ₁₂ (cyanocobalamin)	5 mcg

Inactive ingredients: 30% propylene glycol, citric acid and/or sodium citrate for pH adjustment, and water for injection.

“Aqueous” multiple vitamin preparation for intravenous infusion:

INFUVITE ADULT (PHARMACY BULK PACKAGE) (Multiple Vitamins for Infusion) makes available a combination of important oil-soluble and water-soluble vitamins in an aqueous solution, formulated for incorporation into intravenous solutions. The liposoluble vitamins A, D, E, and K have been solubilized in an aqueous medium with polysorbate 80, permitting intravenous administration of these vitamins.

Contains no more than 70 mcg/L of aluminum (combined Vials 1 and 2).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity, and fertility studies have not been performed with INFUVITE ADULT (PHARMACY BULK PACKAGE).

16 HOW SUPPLIED/STORAGE AND HANDLING

INFUVITE ADULT (PHARMACY BULK PACKAGE) – NDC 54643-5650-2, is available in boxes containing 2 vials – 1 each of Vial 1 (50 mL) and Vial 2 (50 mL Fill in 100 mL Vial). Mix contents of Vial 1 with Vial 2 to provide 10 single doses.

Store under refrigeration, 2-8°C (36-46°F).

17 PATIENT COUNSELING INFORMATION

- Instruct patient that INFUVITE ADULT (PHARMACY BULK PACKAGE) is indicated for the prevention of vitamin deficiency in adults and children 11 and older receiving parenteral nutrition and in patients with extensive burns, fractures and other trauma, severe infectious diseases, and comatose states, or who undergo surgery.
- INFUVITE ADULT (PHARMACY BULK PACKAGE) is contraindicated in patients who have a history of hypersensitivity to any of the vitamins in this product or existing hypervitaminosis due to any vitamins contained in this formulation. Obtain detailed allergy and concomitant drug information from the patient, as well as if they have any kidney or liver impairment and if they are pregnant, prior to INFUVITE ADULT (PHARMACY BULK PACKAGE) administration.
- Tell patients to watch for signs of allergic reactions such as urticaria, shortness of breath, wheezing and angioedema, which have been reported following intravenous administration of thiamine.
- Instruct patients with renal impairment to immediately report signs of hypervitaminosis A, manifested by nausea, vomiting, headache, dizziness, blurred vision, which has been reported in patients with renal failure receiving 1.5 mg/day retinol and in patients with liver disease.
- Instruct patients to report other adverse reactions such as rash, erythema, pruritus, headache, dizziness, agitation, anxiety, and diplopia.
- Instruct patients who are on warfarin anticoagulant therapy to monitor periodically blood prothrombin/ INR levels to determine if the dose of warfarin needs to be adjusted
- Explain the significance of periodic monitoring of blood vitamin concentrations to determine if vitamin deficiencies or excesses are developing and the need to monitor renal function, calcium, phosphorus, aluminum and vitamin A levels in patients with renal impairment.

Manufactured by
Sandoz Canada Inc.
145 Jules-Léger Street
Boucherville, Qc, Canada, J4B 7K8

Distributed by
Baxter Healthcare Corporation
Clintec Nutrition Division
Deerfield, IL 60015 USA

Printed in Canada

December 2012

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